

questionnaires that were not based on patient interviews. The 25 and 18 item RMDQ is a measure of pain and function widely used in low back pain (LBP) trials that was based solely on clinician involvement. **METHODS:** Two US focus groups ($n = 15$) and one UK focus group ($n = 7$) were asked to complete the problem elicitation technique (PET) alongside the RMDQ to determine the relevance of items. The PET measures the importance of concepts based on a series of questions rating the importance of each item on a five-point likert response continuum. To ensure the RMDQ was not missing any relevant items participants were asked several open-ended questions. **RESULTS:** Participants confirmed the content validity of the RMDQ by identifying four areas of importance: pain/discomfort, activities of daily living, sleep problems and emotional impact. Based on the PET, all RMDQ items were rated as moderately to extremely important (item score range of 3.57–4.36 on a one–five scale). Items rated least important were the same items removed in the 18 item version. In the open ended questions, sleep disturbances was consistently mentioned as a primary area of concern. **CONCLUSIONS:** The PET augmented by open-ended questions is a valid method for confirming the content validity of questionnaires that did not include patient involvement in their development. These findings support the continued use of the RMDQ in LBP trials; however, consideration should be given to including additional sleep questions or measuring this concept separately.

Respiratory Diseases

RSI

QUALITY OF LIFE IN ASTHMA PATIENTS IS AFFECTED BY HOME TELEMAGEMENT

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OBJECTIVES: To determine whether Home Automated Telemangement (HAT) affects disease-specific Quality of Life (QOL) in adult asthma patients. **METHODS:** Fifty adult patients with mild persistent to severe asthma were randomly assigned to an intervention or control group and were followed for 12 months. The patients in the control group received regular care. The patients in the intervention group used HAT to monitor and manage their condition. The HAT system assisted clinicians in setting up individualized action plans and helped asthma patients in following their action plans at home using peak flow meter and a laptop connected with a hospital. **RESULTS:** Both intervention and control group patients had similar baseline demographic characteristics with regard to their asthma severity, action plan use, computer skills and the quality of life. After 12-month follow-up the mean total QOL score in the intervention and the control group was 20.2 ± 0.9 and 16.9 ± 1.3 respectively. The difference was significant ($p < 0.0001$) at the alpha level of 0.05. Analysis of the symptoms domain of the asthma quality of life showed improved score 5.3 ± 0.4 in the intervention group compared to the control group 4.4 ± 0.6 ($p < 0.05$). The activities domain of the QOL showed an improvement in the activities in the intervention group 5.1 ± 0.2 compared to the control group 3.7 ± 0.3 ($p < 0.05$). There was a statistically significant difference ($p < 0.05$) in the emotions domain of the QOL: the mean score in the intervention group was 4.8 ± 0.2 whereas the mean score in the control group was 4.4 ± 0.4 . The environment domain in the intervention group was 5.1 ± 0.3 compared to 4.4 ± 0.5 in the control group ($p < 0.005$). **CONCLUSION:** Disease-specific quality of life in asthma patients is positively affected by Home Telemangement.

RS2

ASSESSING HEALTH-RELATED QUALITY OF LIFE USING THE SF-12V2 FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: To assess health-related quality-of-life (HRQOL) for patients with chronic obstructive pulmonary disease (COPD). **METHODS:** In Spring 2004, 700 patients cared for by pulmonologists or general practitioners at 12 sites across the US completed a 90-item survey that included the SF-12v2 and pre-/post-bronchodilator spirometry. COPD was defined as post-bronchodilator Forced Expiratory Volume in one second/Forced Vital Capacity (FEV_1/FVC) $< 70\%$. Descriptive statistics for SF-12v2 measures were calculated for mild ($FEV_1 > 80\%$ predicted) and moderate/severe ($FEV_1 < 80\%$ predicted) COPD. Disease burden was estimated by adjusting general population normative data from the 1998 National Survey of Functional Health Status (NSFHS) to age and sex characteristics of the COPD sample. Multivariate and univariate analyses of variance (MANOVA, ANOVA) F-statistics were used to test for differences between patients' HRQOL and adjusted norms. **RESULTS:** Based on spirometry, 36% ($N = 249$) of patients had COPD (20% mild, 80% moderate/severe). Patients with COPD were less likely to describe their health as very good or excellent (20.5% vs. 36.8%, $p < 0.001$), and more likely to describe their health as fair or poor (33.3% vs. 23.4%, $p < 0.005$) compared to those without COPD. MANOVA revealed a significant difference between the full profile of SF-12v2 scales for COPD patients and the US general population ($p < 0.001$). Adjusted norm comparisons revealed that patients with mild COPD had significantly lower (mean, SD) Role Physical (41.9, 11.1; $p < 0.02$) and Physical Component Summary (PCS) (41.0, 12.0; $p < 0.02$) scores. Moderate/severe COPD patients had large, statistically significant decrements across all SF-12v2 measures. Differences from normative values were most notable for Physical Functioning (38.2, 12.8; $p < 0.001$), PCS (38.9, 11.7; $p < 0.001$), Role Physical (39.7, 11.9; $p < 0.001$), General Health (40.8, 11.2; $p < 0.001$), and Role Emotional (43.0, 13.0; $p < 0.001$). **CONCLUSION:** Compared to the US general population, COPD has a significant impact on a patient's HRQOL, notable with mild disease and pronounced at higher severity levels.

RS3

ESTIMATING THE COST-EFFECTIVENESS OF FLUTICASONE PROPIONATE FOR TREATING CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: To explore the cost-effectiveness of fluticasone propionate (FP) for the treatment of chronic obstructive pulmonary disease (COPD), we estimated costs and quality adjusted life years (QALYs) over three-years, based on an economic appraisal of a previously reported clinical trial (ISOLDE). **METHODS:** Results from the initial analyses of the trial data showed significant improvements with FP in reducing the rate of exacerbations from COPD, in slowing the rate of decline in health status and a trend towards improved survival. A recently